VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 12/12/06

Board Members:

Michael Scovner, M.D., Acting Chair
Andrew Miller, R. Ph.
Cheryl Gibson, M.D.
Frank Landry, M.D.
Norman Ward, M.D.
Richard Harvie, R. Ph.
Stuart Graves, M.D.

Staff:

Ann Rugg, OVHA
David Calabrese, R.Ph., MHP
Diane Neal, R.Ph., MHP
Erin Cody-Reisfield, M.D., OVHA
Jennifer Mullikin, OVHA
Natalie Santamore, OVHA
Robin Farnsworth, OVHA
Ann Bennett, OVHA

Guests:

Andrea Hayes, Sanofi-Aventis
Angelo Valeri, Santarus
Art McNulty, Forest
Carl Pepe, GSK
Carl Possidente, Pfizer
Glenn E. Dooley, Sr, Sanofi-Aventis
Glenn E. Kantarski, VCG & Assoc
Gregg Denton, NovoNordisk
Jenifer Buttle, Merck
John Kowalski, Merck Vaccines
Keith White, Genentech
Maribeth Klettke, Sanofi-Aventis
Mary Kaysen, Takeda
Michael Zdrojewski, ScheringPlough
Ronald Poppel, BMS

Michael Scovner, M.D., Acting Chair, called the meeting to order at 7:12 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Nominations and Election of Chair:

- Introductions were made around the table.
- Michael Scovner, M.D., graciously agreed to act as Chair for this meeting. Ann Rugg has asked Board members to consider if they would be willing to take on the duties of Chair.
- Election of the permanent Chair will occur at the January 2007 meeting.

Public Comment: No public comment.

3. Approval of DUR Board Minutes:

- The November 2006 meeting minutes were accepted as printed without amendment.

4. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- OVHA Pharmacy Bulletin: The first issue of the bulletin has been mailed to pharmacies. A copy was included in the packet so that Board members could view the format. This is designed to be a regular communication vehicle and the hope is that pharmacies will look to the bulletin as a routine source of announcements. The bulletin will also be posted to the OVHA website.

5. Medical Director Update: *Erin Cody-Reisfield, M.D. – Assistant Medical Director, OVHA*

- No updates, prescriber comments, or other topics for discussion.

6. Follow-up items from Previous Meeting

- Wellbutrin XL® (bupropion XL): *David Calabrese, R.Ph, MHP*
  The Board deferred making a decision at the November meeting on whether to add this medication to the PDL and requested additional information. It was confirmed that the manufacturer was offering a 3 year contract on this product. It was recommended that it be added to preferred status on the PDL without restrictions (no step therapy requirements).

Public Comment: No public comment.

Board Decision: The recommendation to add Wellbutrin XL® to preferred status on the PDL without restriction was approved by a vote of 4:3. No commitment was made regarding status of the medication at the end of the 3 year contract. It was agreed that thoughtful discussions around fiscal and clinical considerations would be undertaken as usual at that time.

- Travatan Z® (travoprost): *David Calabrese, R.Ph, MHP*
  The Board deferred making a decision at the November meeting on whether to add this medication to the PDL and requested a price comparison with Travatan®. The two formulations have the same price and Travatan Z® is formulated without the preservative benzalkonium chloride.

Public Comment: No public comment.

Board Decision: The Board voted unanimously to add Travatan Z® to the PDL equally preferred with Travatan® with coverage contingent upon a previous trial of a PDL beta-blocker, alpha-adrenergic, or CAI agent.

- Prevacid Solutabs® (lansoprazole): *Diane Neal, R.Ph, MHP*
  At the November meeting of the DUR Board, Prevacid Solutabs® were moved to PA required for beneficiaries greater than 7 years old effective 01/01/07. A patient specific letter was shared with the Board that was sent to 53 prescribers for 73 patients and outlined alternative proton pump inhibitors choices that are available without PA.

Public Comment: No public comment.

Board Decision: None required.

- Avonex® (interferon β-1a): *Diane Neal, R.Ph, MHP*
  A letter to be sent to prescribers regarding the decision made at the November meeting to remove Avonex® from the PDL was shared with the Board. Current patients will be grandfathered so no action is required on the part of prescribers.

Public Comment: No public comment.

Board Decision: None required.

- Actonel® (risedronate) and Actonel with Calcium®: *Diane Neal, R.Ph, MHP*
  A patient specific letter to be sent to prescribers regarding changes in the ossification enhancer category (bisphosphonates) was shared with the Board. The Board voted in November to remove Actonel® and Actonel with Calcium® from the PDL and to add Boniva® (ibandronate). Prescribers will be asked to move patients from Actonel® and Actonel with Calcium® to a preferred product by 02/01/07. Alternative choices are outlined in the letter.

Public Comment: No public comment.

Board Decision: The Board requested that it be highlighted in the title of the letter that Fosamax® (alendronate) remains on the PDL.

- Simvastatin and Fluticasone PDL Changes: *Diane Neal, R.Ph, MHP*
  A FAX communication to be sent to pharmacies was shared with the Board. Since significant inventory changes may be required to accommodate these PDL changes that become effective 01/01/07, a targeted communication will be sent. Restrictions on the dispensing of generic simvastatin will be removed and Zocor® will become PA required. Generic fluticasone nasal spray will move to PA required while Flonase® will remain as preferred on the PDL.

Public Comment: No public comment.

Board Decision: None required.

- Pharmacy Communication of Other PDL Changes: *Diane Neal, R.Ph, MHP*
  The Board was asked for recommendations for the method of communicating other PDL changes to pharmacies that will occur 01/01/07.

Public Comment: No public comment.

Board Decision: The Board recommended using the OVHA Pharmacy Bulletin as the method to communicate these changes.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, MHP*

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Anti-Obesity Agents: The revised clinical criteria were presented. The criteria were updated to clarify the conditions that would be considered as co-morbid conditions as well as the requirements for a trial of a calorie reduced diet and nutritional counseling. The criteria were updated based on guidelines from the National Heart, Lung, and Blood Institute obesity education initiative. An updated Anti-Obesity Prior Authorization Request Form that reflects the revised clinical criteria was also presented.

Public Comment: No public comment.

Board Decision: The revised clinical criteria and prior authorization request form were unanimously accepted.

- Multiple Sclerosis: Injectables: The revised clinical criteria were presented that reflect the PDL changes approved at the November meeting. Criteria that would allow Avonex® to be approved with PA were presented.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Long Acting Narcotics: The revised clinical criteria, updated to include the move of Duragesic® brand to PA required as voted upon at the November DUR board meeting, were presented. Criteria for Duragesic-12® were presented as well as quantity limits on Duragesic® patches. The Board was also asked to consider further updating the criteria with quantity limits for fentanyl patches and morphine sulfate ER tablets.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted with the addition of quantity limits for both fentanyl patches and morphine sulfate ER tablets.

8. Clinical Update: New Drug Reviews: *Diane Neal, R.Ph. MHP*

- EMSAM® (selegiline) – Not recommended for addition to the PDL. Coverage would require PA and previous trials with at least 3 different antidepressant agents from 2 of the 3 major antidepressant classes (SSRIs, Novel Antidepressants, TCA) with no requirement for an oral MAOI or a documented reason why the patient is unable to tolerate oral medications. A quantity limit of 1 patch per day was recommended.

Public Comment: Ron Poppel, BMS – Commented that EMSAM® is a new option in antidepressant therapy with a unique delivery system that avoids the typical MAOI interaction with tyramine rich foods. He asked that it be added to the PDL for use after failure of other agents.

Board Decision: The Board approved the MHP recommendations noted above.

- Implanon® (etonogestrol implant) – Although contraceptives are not a managed class on the PDL, Implanon ® was reviewed due to cost and concerns with previous implantable devices. It was recommended that Implanon® be covered with no restrictions.

Public Comment: No public comment.

Board Decision: The Board approved the recommendation noted above.

- Taclonex Ointment® (calcipotriene/betamethasone dipropionate) – Not recommended for addition to the PDL. Coverage would require PA and previous trials of a betamethasone dipropionate product and Dovonex® simultaneously with significant non-adherence issues and Tazorac®. A quantity limit of 60 grams at initial fill was recommended.

Public Comment: No public comment.

Board Decision: The Board approved the recommendation noted above with the length of trial of alternative agents defined as 24 months.

9. New Drug Classes: *David Calabrese, R.Ph, MHP*

Note: All drug/criteria decisions from this section will be reflected in the **01/01/07** PDL and/or Clinical Criteria update unless specified otherwise.

- Anemia Medications: Hematopoietic/Erythropoietic Agents
  Proposed PDL preferred agents to be Aranesp® (darbepoetin alfa) and Procrit® (epoetin alpha).
  Proposed non-preferred (PA required) agent to be Epogen® (epoetin alpha). Clinical criteria for approval of Epogen® were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Acne Drugs: Topical Anti-Infectives **(Proposed Effective Date 03/01/07)**
  Proposed PDL preferred agents to be generic benzoyl peroxide, clindamycin, erythromycin, erythromycin/benzoyl peroxide, sodium sulfacetamide and sodium sulfacetamide/sulfur.
  Proposed non-preferred (PA required) agents to include all brand single ingredient and combination products as well as Azelex®. Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Acne Drugs: Topical – Rosacea **(Proposed Effective Date 03/01/07)**
  Proposed PDL preferred agents to be generic metronidazole products.
  Proposed non-preferred (PA required) agents to include all brand metronidazole products and Finacea®. Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Acne Drugs: Topical – Retinoids **(Proposed Effective Date 03/01/07)**
  Proposed PDL preferred agents to be generic tretinoin and Tazorac®.
  Proposed non-preferred (PA required) agents to include all brand tretinoin products and Differin®. Avage®, Solage®, and Tri-Luma® are not indicated for acne and it was recommended that coverage of topical retinoid products not be approved for cosmetic use (wrinkles, age spots etc.). Clinical criteria for approval of brand tretinoin products, Differin® and generic tretinoin for age <10 years or > 34 years were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Acne Drugs: Oral **(Proposed Effective Date 03/01/07)**
  Proposed PDL preferred agents to be generic minocycline, doxycycline, isotretinoin, and erythromycin as well as Sotret®, Claravis®, and Amnesteem®.
  Proposed non-preferred (PA required) agents to include all brand minocycline and doxycycline as well as Accutane®. Clinical criteria for approval of non-preferred agents were presented.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Cardiac Glycosides:
  Proposed that all products be PDL preferred.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Anti-Infectives: Topical Antibiotics
  Proposed that all products be PDL preferred. A board member noted the omission of generic mupirocin ointment from the table.

Public Comment: No public comment.

Board Decision: The Board approved as recommended but the category will be brought back to the January meeting to discuss the addition of mupirocin ointment.

10. RetroDUR: *Diane Neal, R.Ph. MHP*

- No topics for discussion this month.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, MHP*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations but requested that the board consider reviewing Chantix® at the next meeting in January rather than February as scheduled.

12. General Announcements:

- Tamiflu® (oseltamivir phosphate) - *Diane Neal, R.Ph, MHP*
  The FDA and Roche notification to healthcare professionals of safety labeling changes regarding the risk of neuropsychiatric events was presented. There have been postmarketing reports (mainly from Japan) of self-injury and delirium primarily among pediatric patients with the use of Tamiflu® in patients with influenza.

Public Comment: No public comment.

Board Decision: The Board recommended posting the Tamiflu® "Dear Healthcare Provider Letter" on the OVHA web site.

13. Adjourn: Meeting adjourned at 8:37 p.m.

Next DUR Board Meeting
Tuesday, January 16, 2007
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.